# AUROPHEN COLD MULTI SYMPTOM - acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride liquid Aurohealth LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# **Drug Facts**

Active ingredients (in each 15 mL) Acetaminophen 325 mg Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg Phenylephrine HCl 5 mg

# Purpose

# Pain reliever/fever reducer

Cough suppressant Antihistamine Nasal decongestant

#### Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - runny nose and sneezing
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

# **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash.

If a skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

# Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)

# Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

# When using this product

- do not exceed recommended dose
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

# Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

# If pregnant or breast-feeding,

ask a health professional before use.

# Keep out of reach of children.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### Directions

- do not take more than directed (see overdose warning)
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- mL = milliliter

adults and children 12 years and over	<ul> <li>take 30 mL in the dosing cup provided every 4 hours while symptoms last</li> <li>do not take more than 150 mL in 24 hours, unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

#### Other information

- each 15 mL contains: sodium 5 mg
- store at 20-25°C (68-77°F). Do not refrigerate.
- do not use if printed shrinkband is missing or broken
- see back label for lot number and expiration date

# **Inactive ingredients**

alcohol, anhydrous citric acid, FD & C Blue #1, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

# **Questions or Comments?**

1-855-274-4122

#### DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

# Distributed by:

Aurohealth LLC. 2572 Brunswick Pike, Lawrenceville, NJ 08648

# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 8 FL OZ (240 mL Bottle)

**AUROHEALTH** 

NDC 58602-127-20

Compare to the active ingredients in TYLENOL  $^{\$}$  COLD MULTI-SYMPTOM Liquid night time cool burs  $t^{TM^*}$ 

NIGHT TIME

Cool Blast

**AUROPHEN** 

# **COLD MULTI-SYMPTOM**

For Adults

# Acetaminophen - Pain Reliever/Fever Reducer

Phenylephrine HCl - Nasal Decongestant

Dextromethorphan HBr - Antitussive

Doxylamine Succinate - Antihistamine

- Headache, Fever, Sore Throat
- Nasal Congestion
- Cough
- Runny Nose

Alcohol 0.5%

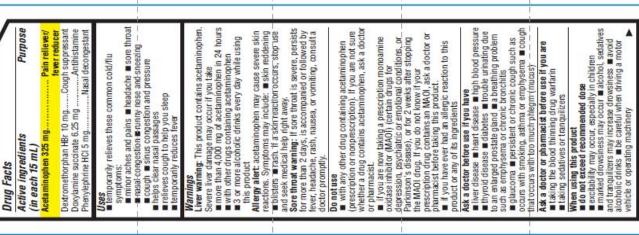
8 FL OZ

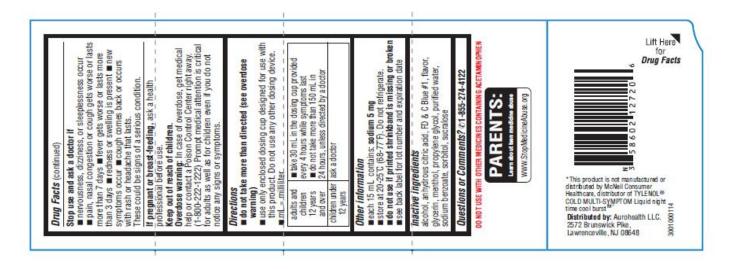
(240 mL)

Liquid

Do not use if printed shrinkband is missing or broken.







#### AUROPHEN COLD MULTI SYMPTOM

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride liquid

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-127
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg in 15 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
<b>DO XYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
PEPPERMINT (UNII: V95R5KMY2B)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SORBITOL (UNII: 506T60A25R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics			
Color	BLUE (Blue to greenish blue)	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 NDC:58602-127-20	1 in 1 CARTON	04/30/2015	03/01/2022
1	240 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/30/2015	03/01/2022

# Labeler - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations

Aurohealth LLC	078728447	MANUFACTURE(58602-127)

Revised: 11/2020 Aurohealth LLC